Appl. No. : 09/380,534
Filed : September 1, 1999

The specific changes to the amended claims are shown on a separate set of pages attached hereto and entitled VERSION WITH MARKINGS TO SHOW CHANGES MADE, which follows the signature page of this Amendment. On this set of pages, the **insertions are double underlined and in bold** while the **[deletions are in brackets and bolded].**

In the Office Action mailed on December 1, 2001, claims 1, 4, 7-10, 14, 39, 43-52, 55-59, and 61-65 were rejected under 35 U.S.C. §102(b) as being anticipated by Martins et al. (U.S. Patent No. 4,455,142) ("Martins"). Further, claims 2, 3, 5-6, 11-13, 15-21 and 40 and 60 were rejected under 35 U.S.C. §103(a) as being unpatentable over Martins in view of various other references, including Kundig (Science 268:1343-1347).

Martins does not anticipate the claims because Martins fails to disclose all of the elements of the claims. Applicants reiterate that Martins does not disclose or enable inducing and/or sustaining an immunological CTL response. Further, at the time the instant invention was made, motivation to apply Martins to the induction of an immunological CTL response was lacking. However, to more clearly and distinctly point out the subject matter of the invention, and to advance the case toward allowance, claim 1 has been amended. Claim 1 as amended recites:

> 1. A method of obtaining a sustained immunological CTL response in a mammal, which method comprises:
>
> delivering an antigen to the lymphatic system of the mammal at a level sufficient to induce an immunologic CTL response in the mammal; and
>
> causing sustained exposure of the antigen to the mammal's lymphatic system by maintaining the antigen in the mammal's lymphatic system over time sufficient to maintain the immunologic CTL response longer than obtainable with an unsustained administration of the antigen distal to the lymphatic system.

Martins does not disclose each and every element of claim 1 as amended. Specifically, Martins does not disclose delivering an antigen to the lymphatic system of the mammal at a level sufficient to induce an immunologic CTL response in the mammal. Further, Martins fails to disclose causing sustained exposure of the antigen to the mammal's lymphatic system by maintaining the antigen in the mammal's lymphatic system over time sufficient to maintain the immunologic CTL response longer than obtainable with an unsustained administration of the antigen distal to the lymphatic system.

With regard to the rejections under §103(a), none of the cited references alone or in combination disclose all of the elements of claim 1. Specifically, as an example, Kundig fails to

disclose sustained exposure of antigen to the lymphatic system by maintaining antigen in the lymphatic system. Thus, Applicants assert that the claims are not anticipated by or obvious in view of any of the cited references.

CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action and during the interview on April 23, 2002. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art. In light of the above remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 31 May 2002

By: _____

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Please amend claims 1, 4, 14, 38, 50-51, and 59-60 as set forth below:

1. **(Twice Amended)** A method of **[inducing and/or sustaining an]** **obtaining a sustained** immunological CTL response in a mammal, which method comprises:

delivering an antigen to **the lymphatic system of** the mammal at a level sufficient to induce an immunologic CTL response in the mammal; and

causing sustained exposure of the antigen to the mammal's lymphatic system by maintaining the antigen in the mammal's lymphatic system over time sufficient to maintain the immunologic CTL response **longer than obtainable with an unsustained administration of the antigen distal to the lymphatic system**.

4. **(Twice Amended)** The method of Claim 1, wherein **[the method is applied to a treatment of a mammal having a disease, or being predisposed to a disease, wherein]** the antigen is a disease matched antigen.

14. **(Twice Amended)** The method of Claim 4 wherein the antigen is delivered to the mammal by pumping a physiologically-acceptable, composition of the antigen from a device held external of the mammal's body through a transmission line **[and catheter]** positioned to deliver the antigen-containing composition so that the antigen reaches the mammal's lymph system.

38. **(Amended)** A process for preparing a system useful for inducing a sustained CTL response in an animal needing such a response, which comprises:

placing a physiologically-acceptable, aqueous, antigen-containing composition in a reservoir having a pump **adapted** for delivering the composition at a defined rate through a transmission line to **the lymphatic system of** the animal.

50. **(Amended)** The method of claim **[49]1**, wherein **[the expression vector further comprises]** **said antigen is provided as a vector comprising** a bacterium.

51. **(Amended)** The method of claim **[48]1**, wherein **[the expression vector further comprises]** **said antigen is provided as a vector comprising** a virus.

59. **(Amended)** The method of claim 48, wherein said antigen is **[provided as]** a polypeptide.

60. **(Amended)** The method of claim 59, wherein said **[antigen]** **polypeptide** consists of about 8-10 amino acids.